UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,932	09/09/2003	David N. Ku	8537-3	3113

20792 7590 01/26/2007
MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
WILLSE, DAVID H	
ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,932	KU, DAVID N.	
	Examiner	Art Unit	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 34-73* is/are pending in the application.

4a) Of the above claim(s) *8,10-12,27,53-55 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,13-26,28,29,34-52,56-69 and 71-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-27-06; 8-2-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 23, line 2, it is unclear as to whether "made of a single solid elastomer" is supposed to modify "endplates" or "body".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 7, 9, 13-25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickman, US 7,066,960 B1. An ultimate strength in tension generally greater than about 100 kPa would have been immediately obvious, if not inherent, from the reinforcing nature of the fabric (column 7, lines 49-55) and from the tensile strength required of a ligament (column 10, line 6 et seq.). Since the claimed value of 0.01 N-m is a *minimal* torsion value, the Dickman device being capable of at least two degrees of rotation would likewise have been immediately

obvious, if not inherent, from the fact that the implant can resiliently absorb stresses associated with spinal rotation and the like (column 1, lines 25-30; column 5, lines 33-64; column 8, lines 49-54). The particular strengths set forth in present claims 2, 3, and others would have been obvious for similar reasons. Regarding claim 13 and others: column 6, lines 25-33; column 8, lines 29-45; etc.

Claims 1-7, 9, 13-26, 28, 29, 34-52, 56-69, and 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickman, US 7,066,960, in view of Oka et al., US 5,458,643, and Schmieding, U.S. provisional application no. 60/412,028 (via US 2004/0059425 A1). Dickman is unspecific as to the *types* of hydrogel polymers that can be used but does mention PVA hydrogel at column 4, lines 49-55, in reference to Oka et al. Since Oka et al. teach that reinforced PVA hydrogels are advantageous for both artificial articular cartilage and artificial intervertebral discs (abstract), one of ordinary skill would have been motivated to consider pertinent references in both of the related arts. Schmieding discloses that SALUBRIA, a hydrogel composition similar to human tissue in its physical properties (paragraph **0002**), can be molded into anatomic shapes and is very suitable for orthopedic applications, including osteochondral implants (paragraph **0003**). The Dickman hydrogel polymer being SALUBRIA would thus have been obvious to the ordinary practitioner in order to ensure reduced wear, adequate strength, and fatigue resistance (Schmieding: paragraph **0003**), with further motivation being provided by the fact that all three documents are directed towards imparting sufficient strength and the like to hydrogel materials. The further limitation of claim 42 would have been obvious from column 8, lines 14-17, of Dickman. Regarding claim 43 and others, the upper and lower surfaces of the embodiments shown in Figures 6, 7, and 9-11 of Dickman each possess

concave, convex, and substantially flat peripheral surfaces, particular when the implant is subjected to various stresses typically encountered during use (column 8, lines 10-11), and such would also have been obvious in order to supplement fixation of the device.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dave Willse
Primary Examiner
Art Unit 3738